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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,773	02/10/2004	Aya Jakobovits	511582005020	3468

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,773	JAKOBOVITS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 28 and 39, drawn to a composition comprising a protein of Figure 2, classified in class 530, subclass 350.

II. Claims 11-14, 16 and 39, drawn to a polynucleotide that encodes a protein of Figure 2, classified in class 536, subclass 23.5.

III. Claim 15, 29 and 39, drawn to an 158P1D7 siRNA composition that comprises double stranded RNA that corresponds to the nucleic acid ORF sequence of a 158P1D7 protein, classified in class 536, subclass 23.1.

IV. Claims 17-21, drawn to a method of generating a mammalian immune response comprising exposing cells to an immunogenic portion of 158P1D7-related protein that comprises at least one T cell or B cell, classified in class 435, subclass 325. Claim 17 will be examined with this Group to the extent that the method involves exposing cells to a protein.

V. Claim 17, drawn to a method of generating a mammalian immune response comprising exposing cells to a nucleotide sequence that encodes a 158P1D7-related protein, classified in class 436, subclass 174. Claim 17 will be examined with this Group to the extent that the method involves exposing cells to a nucleic acid.

VI. Claim 22, drawn to a method for detecting the presence of mRNA, which encodes a protein of Figure 2, classified in class 436, subclass 63.

VII. Claims 23-27, drawn to a method for detecting the presence of a 158P1D7-related protein comprising contacting a sample with an antibody, classified in class 436, subclass 536. Claims 23-37 will be examined with this Group to the extent that the assay detects protein utilizing an antibody.

VIII. Claims 23-27, drawn to a method for detecting the presence of a 158P1D7-related polynucleotide comprising contacting a sample with a substance that binds to the 158P1D7-related polynucleotide, classified in class 536, subclass 24.1. Claims 23-37 will be examined with this Group to the extent that the assay detects nucleic acid.

IX. Claims 28, 30-34 and 36-39, drawn to a composition comprising a substance that modulates the status of a cell that expresses a protein of Figure 2, wherein the substance comprises an antibody, a pharmaceutical composition that comprises said antibody and a hybridoma that produces said antibody, classified in class 530, subclass 387.1. Claims 28 and 39 will be examined with the instant Group to the extent the composition comprises an antibody.

X. Claim 35, drawn to a non-human transgenic animal, classified in class 800, subclass 6.

XI. Claims 28 and 39, drawn to a composition comprising a substance that modulates the status of a cell that expresses a protein of Figure 2, wherein the substance comprises a polynucleotide that encodes an

antibody that binds to a protein of Figure 2, classified in class 536, subclass 22.1. Claims 28 and 39 will be examined with the instant Group to the extent the composition comprises a polynucleotide.

XII. Claims 28 and 39, drawn to a composition comprising a substance that modulates the status of a cell that expresses a protein of Figure 2, wherein the substance comprises a ribozyme that cleaves a polynucleotide having a 158P1D7 coding sequence, classified in class 435, subclass 91.31. Claims 28 and 39 will be examined with the instant Group to the extent the composition comprises a ribozyme.

XIII. Claims 28 and 39, drawn to a composition comprising a substance that modulates the status of a cell that expresses a protein of Figure 2, wherein the substance comprises human T cells that recognize a 158P1D7 peptide subsequence, classified in class 435, subclass 325. Claims 28 and 39 will be examined with the instant Group to the extent the composition comprises T cells.

IX. Claims 40, 41 and 47, drawn to a method of inhibiting growth of cancer cells that express a protein of Figure 2 comprising administering to the cells an antibody composition, classified in class 424, subclass 130.1. Claims 40 and 47 will be examined with this Group to the extent the method reads on an antibody composition.

X. Claims 40, 42 and 47, drawn to a method of inhibiting growth of cancer cells that express a protein of Figure 2 comprising administering to the

cells a 158P1D7-related protein, classified in class 530, subclass 350. Claims 40, 42 and 47 will be examined with this Group to the extent the method reads on a polypeptide composition.

XI. Claims 40, 42 and 47, drawn to a method of inhibiting growth of cancer cells that express a protein of Figure 2 comprising administering to the cells a polynucleotide comprising a coding sequence for a 158P1D7-related protein, classified in class 514, subclass 44. Claims 40, 42 and 47 will be examined with this Group to the extent the method reads on a polynucleotide composition.

XII. Claims 40, 43 and 47, drawn to a method of inhibiting growth of cancer cells that express a protein of Figure 2 comprising administering to the cells a ribozyme that cleaves a polynucleotide that encodes a protein of Figure 2, classified in class 435, subclass 91.31. Claims 40 and 47 will be examined with this Group to the extent the method reads on a ribozyme composition.

XIII. Claims 40, 44 and 47, drawn to a method of inhibiting growth of cancer cells that express a protein of Figure 2 comprising administering a composition comprises human T cells, classified in class 424, subclass 9.1. Claims 40 and 47 will be examined with this Group to the extent the method reads on a human T cell composition.

XIV. Claims 40, 45 and 47, drawn to a method of inhibiting growth of cancer cells that express a protein of Figure 2 comprising administering a

composition comprises a vector that delivers a nucleotide that encodes a single chain monoclonal antibody, classified in class 536, subclass 22.1. Claims 40 and 47 will be examined with this Group to the extent the method reads on a vector that delivers a nucleotide cell composition.

XV. Claim 46, drawn to a method of delivering an agent to a cell that express a protein of Figure 2 comprising providing the agent conjugated to an antibody, classified in class 530, subclass 387.1.

XVI. Claims 48 and 49, drawn to a method of targeting information for preventing or treating a cancer of a tissue comprising detecting the presence or absence of the expression of a polynucleotide in Figure 2, classified in class 435, subclass 6.

XVII. Claims 50-53 and 55-58, drawn to a method for identifying a candidate molecule that modulates cell proliferation comprising introducing a test molecule, classified in class 435, subclass 4.

XVIII. Claim 54, drawn to a method for treating a cancer of a tissue comprises administering a candidate molecule, classified in class 514, subclass 1.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-III and IX-XIII are structurally and functionally different products, which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups IV-VIII and XIV-XXIII differ in the method objectives, method steps and parameters in the reagents used.

Inventions I-III and IX-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions drawn to products are patently distinct and made by different processes. The polypeptides of Group I are a linear order of amino acid residues, whereas the products of Groups II and XI are deoxyribonucleic acids (DNA), unbranched polymers composed of four subunits. Group III is a small inhibitory RNA (siRNA), which could turn off the activity of a gene. The antibody product of Group IX are a complex of glycoproteins. Group X is drawn to a non-human transgenic animal that has a deliberate modification within its genome, foreign DNA is introduced into the animal, using recombinant DNA technology. A ribozyme of Group XII is an RNA molecule that catalyzes a chemical reaction. And the T cells of Group XIII are a member of white blood cells known as lymphocytes and play a central role in cell-mediated immunity.

Inventions IV and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of these two method Groups both implement a protein of Group I, however they have two different endpoints. The Invention of Group IV is a method

drawn to generating an immune response, whereas the Invention of Group XV is drawn to inhibiting the growth of cancer cells.

Inventions V, XI and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of method Groups V, XI and XIX all implement polynucleotides, but result in different method endpoints.

Inventions IX and VII, XIV, XIX and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the antibody of Group IX could be used in any of the methods of Inventions VII, XIV, XIX and XX.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
29 September 2006